K012722

SEP 1 8 2001

Summary of Safety and Effectiveness
Lyphochek® Coagulation Control

1.0 Submitter

Bio-Rad Laboratories
9500 Jeronimo Road,
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
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Date of Summary Preparation

August 15, 2001

2.0 Device Identification

Product Trade Name:	Lyphochek® Coagulation Control
Common Name:	Plasma Coagulation Control
Classifications:	Class II
Product Code:	GGN
Regulation Number:	21 CFR 864.5425

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek® Coagulation Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K990858

4.0 Description of Device

Lyphochek® Coagulation Control is prepared from human plasma, with added purified biochemical and preservatives. The control is provided in lyophilized form for increased stability.

5.0 Statement of Intended Use

Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems

6.0 Comparison of the new device with the Predicate Device

The new Lyphochek® Coagulation Control claims substantial equivalence to the Lyphochek® Coagulation Control currently in commercial distribution (K990858). The new Lyphochek® Coagulation Control does not contain constituents of animal origin and the current product does.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Lyphochek® Coagulation Control (New Device)	Bio Rad Lyphochek® Coagulation Control (Predicate Device)
Similarities		
Intended Use	Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.	Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.
Form	Lyophilized	Lyophilized
Matrix	Human plasma	Human plasma
Storage (Unopened)	2-8°C until expiration date	2-8°C until expiration date
Analytes	Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin II (AT III) Thrombin Time (TT)	Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin II (AT III) Thrombin Time (TT)
Differences		
Open Vial Claim	24 hours at 2-8°C	24 hours at 2-25°C
Formulation	Does not contain constituents of animal origin	Contain constituents of animal origin
Catalog Number	781, 782, 783	787, 788, 789
Fill size	1 mL	2 mL

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Lyphochek® Coagulation Control. Product claims are as follows:

7.1 Open vial: Once the control material is reconstituted, all analytes will be stable for 24 hours when stored tightly capped at 2-8°C

7.2 Shelf Life: Two years when stored at 2-8 °C

7.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: k012722
Trade/Device Name: Lyphochek® Coagulation Control
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: August 15, 2001
Received: August 15, 2001

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K012722

Device Name: Lyphochek® Coagulation Control

Indications for Use:

Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.

Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen and Antithrombin III (AT III) are assayed on the MLA ELECTRA series. Thrombin Time (TT) is assayed on the Dade BBL Fibrometer (Becton Dickinson).

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012722